MRIGlobal

Synthesis Capabilities

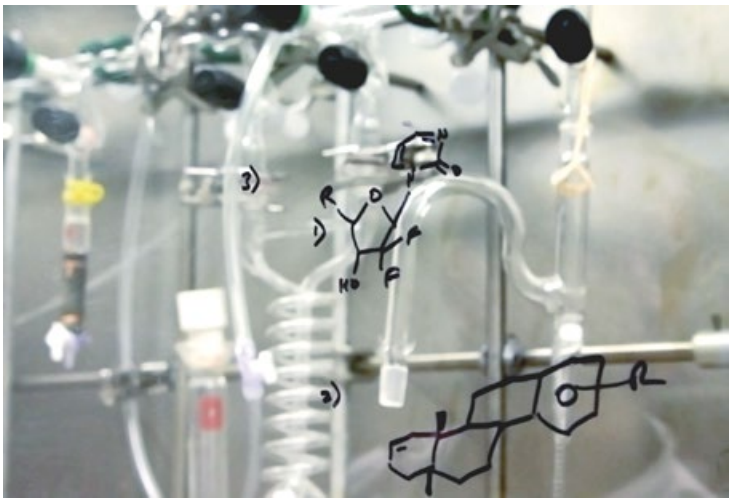
Integrated Pharmaceutical Sciences

API DEVELOPMENT AND CUSTOM SYNTHESIS

- GMP material preparation
- GLP manufacturing and characterization for preclinical studies
- Specialize in complex compounds
  - Novel synthesis route design and process development
  - Stable isotope-labeled compound synthesis (^{2}H, ^{13}C, ^{15}N)
  - Comprehensive analytical support services for confirmation of product identity
  - Assessment of product purity, impurity profiling, commercial supply, and technology transfer packages
- Accommodate synthesis projects that range from simple small molecules to the most challenging and complex compounds

QUALITY ASSURANCE

- QA program, an independent unit within MRIGlobal, ensures all work meets stringent client-specific and quality and regulatory agency requirements.
  - ISO 9001:2015 certified
  - QAU audits
  - On-site staff
  - GMP and/or GLP compliant (FDA 21 CFR 210/211, 21 CFR 58, EPA 40 CFR 160)
- GMP compliant chemical storage with quarantine for raw materials, intermediates, and finished products



OUR CAPABILITIES

- High-quality custom synthesis of compounds in sample sizes ranging from milligram to kilogram quantities
- Unambiguous confirmation of the purity and identity via physical, chromatographic, and spectroscopic analyses
- Controlled substance R&D and manufacturing capability (Schedule II to Schedule V)
- Analytical services (chromatography, spectroscopy, spectrometry, thermal analysis, physical and stability testing; qualitative/quantitative)
- Guarantee the identity and purity of our products through rigorous analysis
- All products are delivered with a comprehensive Certificate of Analysis summarizing the analytical results and a Safety Data Sheet
- GLP characterization of the final product can be performed for regulatory submissions

API SYNTHESIS FACILITIES

- R&D, GLP and GMP synthesis laboratories for discovery, process research and Phase 1 needs
- Ability to handle potent, cytotoxic and controlled substances
- Multiple reactor configurations ranging from 5 L to 100 L for chemical synthesis (mg to 5 kg) and separations
- Vacuum distillation equipment up to 20 L
- Milling declumping
- Vacuum tray dryer
- Lyophilization
- Preparative and semi-prep liquid chromatography
- Temperature range from -80° C to +140° C

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MRIGlobal | Repository Management

Integrated Pharmaceutical Sciences

CUSTOMIZED SOLUTIONS FOR PRODUCT DEVELOPMENT

MRIGlobal helps pharmaceutical clients accelerate their timeline and reduce the risks of getting a product to market by providing customized solutions to their product program. We bring a long history of diverse technical and regulatory expertise as well as a legacy of integrity and collaboration to make certain each client's objectives are achieved - on time and on budget.

OUR FULL SERVICES INCLUDE:

- Analytical Method Development and Phase Appropriate Validation for API DS & DP, Intermediates, and Impurities
- Bioanalytical Method Development and Validation, and Sample Analysis for Analyte Quantitation in Multiple Species and Matrices
- GLP and cGMP Stability and Storage of Drug Substances and Drug Products
- Custom Synthesis, Preclinical Batch Preparation and GLP Characterization, and Metabolite/Impurity Synthesis

ABOUT MRIGLOBAL

Founded in 1943, MRIGlobal is an independent organization performing customized contract scientific and engineering research, as well as management and operations, for government and industry around the globe.

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